

Guidance for Industry

SURVEILLANCE AND DETENTION WITHOUT PHYSICAL EXAMINATION OF SURGEONS' AND/OR PATIENT EXAMINATION GLOVES

Draft Guidance – Not for Implementation

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**General Hospital Devices Branch
Division of Enforcement II
Office of Compliance**

Preface

Public Comment:

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. 00D-1384, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20857.

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GUIDANCE FOR SURVEILLANCE AND DETENTION WITHOUT PHYSICAL EXAMINATION OF SURGEONS' AND/OR PATIENT EXAMINATION GLOVES¹

(Recidivist Policy)

This Recidivist Policy represents the Food and Drug Administration's (FDA) guidance to Agency personnel regarding manufacturers/shippers who continually export defective medical gloves to the United States.

BACKGROUND

Health care professionals and others use surgeons' and/or patient examination gloves as a barrier to blood-borne diseases and pathogens. Poor quality medical gloves present a possible hazard to health for users as well as patients. The Center for Devices and Radiological Health (CDRH) has found that many foreign manufacturers and shippers of medical gloves consistently fail to provide gloves of adequate quality for distribution into the United States. Therefore, continuous monitoring of these devices is necessary.

This draft guidance is intended to provide guidance to staff and industry about a recidivist policy for firms that repeatedly attempt to import surgeons' and patient exam gloves that

¹ This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

violate quality requirements. FDA's experience with sampling, examination, and testing of surgeons' and/or patient examination gloves raises concerns about the barrier properties of some gloves exported to the United States. Our analyses of surgeons' and patient examination gloves exported to the United States show a significant variation in the quality of the gloves exported by various manufacturers/shippers. We repeatedly place the same manufacturers/shippers on import detention due to leaks and defects in their gloves. These firms then need to provide us with private laboratory analyses for a number of shipments in order to demonstrate that the quality of the gloves and the firm's manufacturing operations comply with FDA standards. Once the firms provide such evidence, we remove them from import alert. However, many of these same manufacturers/shippers have repeated violative analyses and return to import alert status. This cyclical problem of violations requires continuous auditing and monitoring of recidivist firms to prevent the entry of defective gloves into the United States.

In an attempt to ensure that surgeons' and /or patient examination gloves exported to the United States are in compliance with FDA standards, we revised Import Alert #80-04, "Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves," referred to as the "Recidivist Policy." This initiative was a joint effort between the Agency's Center for Devices and Radiological Health's Office of Compliance, ORA's Division of Import Operations and Policy, and the Office of Chief Counsel.

The Recidivist Policy defines three increasingly stringent compliance levels for firms who have shipped violative surgeons' and patient examination gloves to the United States. Levels 1 and 2 allow voluntary compliance opportunities, while Level 3 provides a mechanism to issue a Warning Letter for Apparent Violations of the Act, including noncompliance with the Quality Systems regulation for Good Manufacturing Practices. A finding of Level 3 noncompliance will automatically place any future shipments of surgeons' or patient examination gloves from the manufacturer/shipper on detention, without the need for FDA to perform an actual inspection at the manufacturer, due to the continued failure of the surgeons' and/or patient examination gloves to pass minimum FDA standards upon import.

Legal Charges for Defective Gloves

When there is evidence that shipments of surgeons' and/or patient examination gloves contain defects/holes, they may be refused entry into the United States under section 801(a)(3) of the Food, Drug, and Cosmetic Act (the Act) because they appear to be of substandard quality. This means that these defective gloves are considered adulterated under section 501(c) of the Act.

When FDA documents repeated shipments of violative products, the agency may issue the manufacturer or shipper a Warning Letter (for failure to manufacture the device in conformance with the Quality System Regulation in addition to the charges discussed above) in accordance with the Recidivist Policy outlined later in this document. In

addition, when a pattern of recidivism creates an appearance of violation of the Quality System Regulation and FDA issues a Warning Letter to a particular firm, FDA may also refuse entry of the surgeons' and/or patient examination gloves manufactured or shipped by that firm under section 801(a)(1) of the Act because the methods, facilities, and controls used to manufacture, package, and store the gloves appear to be out of conformance with the Quality System Regulation. [Title 21, Code of Federal Regulations (CFR) Part 820; promulgated under section 502 (f)(i) of the Act.] The gloves are therefore adulterated under section 501(h) of the FD&C Act.

Guidance to FDA Field Offices

FDA district offices may detain, without physical examination, all shipments of surgeons' and/or patient examination gloves from manufacturers/shippers listed on FDA's Import Alert #80-04 Attachments A and B. Surveillance sampling of surgeons' and/or patient examination gloves from manufacturers/shippers that do not appear on Import Alert #80-04 Attachments A and B should be performed according to the latest guidance.

Because the presence of defects/holes in surgeons' and/or patient examination gloves may present a possible hazard to health, only one (1) defective sample is needed to recommend detention without physical examination to FDA's Division of Import Operations & Policy (DIOP). DIOP has direct authority to detain, without physical examination, any defective medical gloves without the approval of CDRH. In addition,

the subchapter called “Recommendations Based on One Sample” in Chapter 9 of the Regulatory Procedures Manual contains guidance for defective gloves.

Recidivist Policy

The following strategy provides guidance to the field concerning manufacturers/shippers who repeatedly export defective medical gloves to the United States. Such manufacturers/shippers are identified as “recidivist” firms. Three levels of detention are addressed in the Recidivist Policy as follows:

Level 1 Detention: Firms on Level 1 detention are listed in Attachment A of Import Alert #80-04 and are indicated by an “*” beside their name. These include firms that have failed FDA analysis for the first time, as well as firms that have recently been removed from Level 3.

When a shipment of surgeons’ and/or patient examination gloves contains defective gloves and is found violative, based on FDA laboratory testing, the shipment should be detained. A recommendation for detention of future shipments without physical examination should be sent to DIOP at HFC-170. Firms will be placed on Import Alert #80-04 only for two categories of gloves: “surgeons’ gloves” and/or “patient examination gloves.” Specific types/styles of gloves (powdered, powder-free, vinyl, nitrile etc.) are not considered separate glove categories for the purposes of the Recidivist Policy and should not be referenced in a recommendation for detention. DIOP will review the recommendation to ensure the circumstances support detention without physical examination, as discussed in this guidance.

If the recommendation supports detention under the Act, as implemented by the recidivist policy described in this document, the manufacturer/shipper will be placed on Attachment A of Import Alert #80-04 and an “*” will be placed beside the firm name. Any subsequent shipments from that manufacturer/shipper of gloves listed on the alert (i. e. “surgeons’ gloves” and/or “patient examination gloves”) may be detained without physical examination, including types, styles, or brands of gloves that were not specifically found violative by testing. The manufacturer/shipper may obtain entry of subsequent shipments by presenting evidence that the individual shipments are not adulterated. Evidence may include sample testing performed by an independent laboratory in the United States. The testing performed should follow the sampling plan and test methods contained in current Title 21 CFR Section 800.20.

In order for the responsible manufacturer/shipper to be removed from Level 1 detention, the firm should provide documentation that contains sufficient evidence to show that its surgeons’ and/or patient examination gloves are not adulterated. Evidence which shows that five consecutive medical glove shipments are non-violative, based on valid testing such as FDA’s sampling plans and test methods, may be considered adequate evidence to remove the manufacturer/shipper from Level 1 detention.

Level 2 Detention: Firms on Level 2 detention are listed in Attachment A of Import

Alert #80-04 and are indicated by an “**” beside their name. These include firms that fail FDA or private lab analysis while on Level 1 detention, or firms that have a violative shipment within 24 months after being removed from Level 1.

If a manufacturer/shipper currently on Level 1 detention has a sample tested by a private laboratory, and the sample contains defects that cause the shipment to be violative, the district import operations staff at port of entry should notify DIOP and submit supporting documentation. This information enables DIOP to place the firm on Level 2 detention and identify the manufacturer/shipper on Attachment A of Import Alert #80-04 with two asterisks “**”.

If a manufacturer/shipper was removed from Level 1 detention, but within 24 months from the date the firm was removed from Level 1 detention, has another violative sample based on FDA laboratory test results, the district at the port of entry should notify DIOP and submit supporting documentation. DIOP will then verify that the manufacturer/shipper was on Level 1 detention during the previous 24 months and, if confirmed, should place the firm on Level 2 detention. The manufacturer/shipper will be identified on Attachment “A” of Import Alert #80-04 with two asterisks “**”. DIOP will notify CDRH.

When DIOP places a firm on Level 2 detention, CDRH will notify the foreign firm in writing of the concerns about possible deficiencies in the manufacturing practices and process controls that may be affecting the quality of the gloves shipped to the United States. A copy of the Quality System Regulation for Medical Devices will be attached to the letter for the firm's information (21 CFR part 820).

Before removing a firm from Level 2 detention without physical examination, FDA may need greater assurance that the surgeons' and/or patient examination gloves are not adulterated than that needed for removal from Level 1. Evidence documenting 10 consecutive non-violative shipments, as tested by an independent laboratory in the U.S., may be considered adequate to demonstrate that the firm is shipping surgeons' and patient examination gloves to the United States that are not violative. Other types of evidence to remove the appearance of a violation will be evaluated by CDRH on a case-by-case basis.

Level 3 Detention: Firms on Level 3 detention are listed in Attachment B of

Import Alert #80-04. These include firms that fail FDA or private lab analysis while on Level 2 detention, or firms that were removed from Level 2 detention, and have another violative shipment within 24 months from the date FDA either removed the firm from Level 1 detention status or increased the status to Level

2 detention. These firms are initially listed in Attachment A of IA #80-04 with three asterisks “***” until CDRH has issued a Warning Letter to the firm. These firms will be listed on Attachment B of IA #80-04 after the Warning Letter is issued. Firms on Attachment B will not be allowed to enter their gloves into the U.S., and will remain on Attachment B until they demonstrate conformance with the Quality System Regulation. Such evidence may consist of an inspection by FDA, or certification by the manufacturer of conformance to the Quality System Regulation based on an audit by a qualified third party.

If a manufacturer on Level 2 detention has another violative sample analyzed by an independent testing laboratory in the U.S., the district at the port of entry should notify DIOP and submit supporting documentation. If a manufacturer/shipper that was previously removed from Level 2 detention has another violative sample based on FDA laboratory test results within 24 months from the date FDA either removed the firm from Level 1 detention status or moved the firm to Level 2 detention, the district at the port of entry should notify DIOP and submit supporting documentation. DIOP will notify CDRH.

DIOP and CDRH will verify the manufacturer/shipper has previously been on detention two times during the past 24 months, and, if confirmed, DIOP will place the manufacturer/shipper on attachment "A" with three asterisks (***)).

Based on the failure of the manufacturer's/shipper's surgeons' and/or patient examination gloves to pass FDA testing after removal from Level 2 detention, as discussed above, or having failed an independent laboratory test in the U.S. while on Level 2 detention, FDA may issue a Warning Letter to the firm. If supported by CDRH's review of the manufacturer's import and inspection history, this Warning Letter may include an adulteration charge under section 501(h) of the Act for apparent deviations from the Quality System regulation evident by repeated testing failures (see the Legal Charges for Defective Gloves section above).

When a Warning Letter for Quality System deficiencies is issued, DIOP should place the manufacturer/shipper on Level 3 detention and the manufacturer/shipper should be placed on Attachment B of Import Alert #80-04.

Testing to determine if a shipment is non-violative may not be sufficient to remove the appearance of a violation for manufacturers/shippers on Level 3 detention.

Manufacturers/shippers will remain on Level 3 detention until they can demonstrate that the surgeons' and/or patient examination gloves are manufactured in accordance with the Quality System regulation for Good Manufacturing Practices. The type of evidence that may be considered adequate would include an acceptable FDA on-site inspection of the

manufacturing facilities, or a written certification of conformance with the Quality System Regulation provided by the manufacturer/shipper, together with the results of an independent audit performed by a qualified third party.

After the manufacturer/shipper shows that the apparent Quality System regulation deficiencies have been corrected, the manufacturer/shipper will be removed from Level 3 detention and taken off Attachment B, Import Alert #80-04. The manufacturer/shipper then will be placed on Level 1 detention and listed on Attachment A of Import Alert #80-04 with one asterick “*”. Placement on Level 1 indicates the need for individual shipment testing to confirm that the surgeons’ and/or patient examination gloves do not contain defects. Adequate evidence to be removed from Level 1 detention, at this point, may be five consecutive shipments that pass independent laboratory testing.

Questions or issues concerning science, science policy, sample collection, testing, preparation, or analytical methodology should be forwarded to the Division of Field Science at (301) 443-3320 or (301) 443-3007.

Questions concerning Title 21 CFR, part 820, Compliance Policy Guide 7124.31, medical glove labeling, or other compliance issues should be forwarded to Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement II, General Hospital Devices Branch at (301) 594-4618.

SAMPLING

All sizes should be represented in the sample collected as closely as possible in the proportion in which they exist in the shipment. Exact statistical representation is not necessary. If a sample is found violative, all sizes should be detained.

When an entry consists of only one size, attempt to collect as many lot numbers as possible. For example, if during a random sample collection three lot numbers are observed, the sample should represent all of the lots as sub-samples within one sample. If the sample is found violative, all lots should be detained.

If a shipment is detained based on the testing of one lot and subsequently it is learned that there were 10 lot numbers present, the entire shipment should be detained.